PATENT
Attorney Docket No. 03804.0111-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Rule 53(b) Continuation Application of:	)	
Didier BRANELLEC et al.	)	
Parent Application No.: 08/633,769	)	Parent Group Art Unit: 1632
Parent Filed: June 20, 1996	)	Parent Examiner: S. PRIEBE

For: GENE THERAPY FOR RESTENOSIS USING AN ADENOVIRAL VECTOR

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to the examination of this application, please amend it as follows:

IN THE SPECIFICATION:

Please amend the specification as follows:

Page 1, between lines 2 and 3, insert the following new paragraph:

-- This application is a continuation application of U.S. application Serial No. 08/633,769, filed June 20, 1996, now allowed, the entire disclosure of which is incorporated herein by reference.--

IN THE CLAIMS:

Please cancel claims 1-35 without prejudice to, or disclaimer of, the subject matter contained therein.

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Please add new claims 36-44 as follows:

-- 36. (New) A pharmaceutical composition comprising a human or canine replication defective recombinant adenovirus comprising a suicide gene impregnated in a hydrogel in an amount effective for inhibiting a decrease in luminal diameter of an atheromatous blood vessel when administered to a site of physical damage to said blood vessel.

37. (New) The pharmaceutical composition of claim 37, wherein the adenovirus infects at least 0.2% of smooth muscle cells of the neointima.

38. (New) The pharmaceutical composition of claim 36, wherein said replication defective recombinant adenovirus comprises:

a suicide gene operably linked to a promoter controlling expression of said gene in infected cells;

a left and a right inverted terminal repeat (ITR); and

an encapsidation signal.

39. (New) A device for percutaneous administration of a therapeutic gene, said device comprising a balloon catheter coated with a hydrogel impregnated with a defective recombinant adenovirus comprising said gene, wherein said defective recombinant adenovirus is present in an amount effective for inhibiting a decrease in luminal diameter of an atheromatous blood vessel when administered to a site of physical damage to said blood vessel.

40. (New) The device of claim 39, wherein said defective recombinant adenovirus comprises:

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a suicide gene operably linked to a promoter controlling expression of said gene in infected cells;

a left and a right inverted terminal repeat (ITR); and

an encapsidation signal.

41. (New) A method for inhibiting a decrease in luminal diameter of an atheromatous blood vessel, said method comprising administering a therapeutic gene to said atheromatous blood vessel using a device comprising a balloon catheter coated with a hydrogel impregnated with a defective recombinant adenovirus comprising said therapeutic gene,

wherein said defective recombinant adenovirus is present in an amount effective for inhibiting a decrease in luminal diameter of said atheromatous blood vessel when administered to a site of physical damage to said blood vessel.

42. (New) The method of claim 41, wherein said defective recombinant adenovirus comprises:

a suicide gene operably linked to a promoter controlling expression of said gene in infected cells;

a left and a right inverted terminal repeat (ITR); and

an encapsidation signal.

43. (New) The method of claim 41, wherein the adenovirus infects cells in the artheromatous blood vessel.

44. (New) The emthod of claim 43, wherein 95% of the cell infected are smooth muscle cells.--

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IN THE DRAWINGS:

Please replace the formal drawings filed with the application with the formal drawings attached hereto as part of the Submission of Formal Drawings.

REMARKS

By this Preliminary Amendment, the specification is amended, new formal drawings are submitted, claims 1-35 are cancelled, and new claims 36-44 are added. The specification is amended solely to include continuity data. New formal drawings are submitted to satisfy the requirements of 37 C.F.R. § 1.84 and/or § 1.152. Support for new claims 36-44 comes, for example, from the specification, as originally filed, at page 3, line 1 through page 4, line 8; page 6, line 1 through page 7, line 7; page 10, lines 6-9; and page 11, line 11 through page 12, line 17. Accordingly, no new matter is added.

Currently, claims 36-44 are pending in this application. Early and favorable examination on the merits is earnestly requested.

If any fees are due in addition to those submitted herewith, please charge the fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: _____

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Reg. No. 46,249
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Date: February 21, 2002

Attachment:
Submission of Formal Drawings

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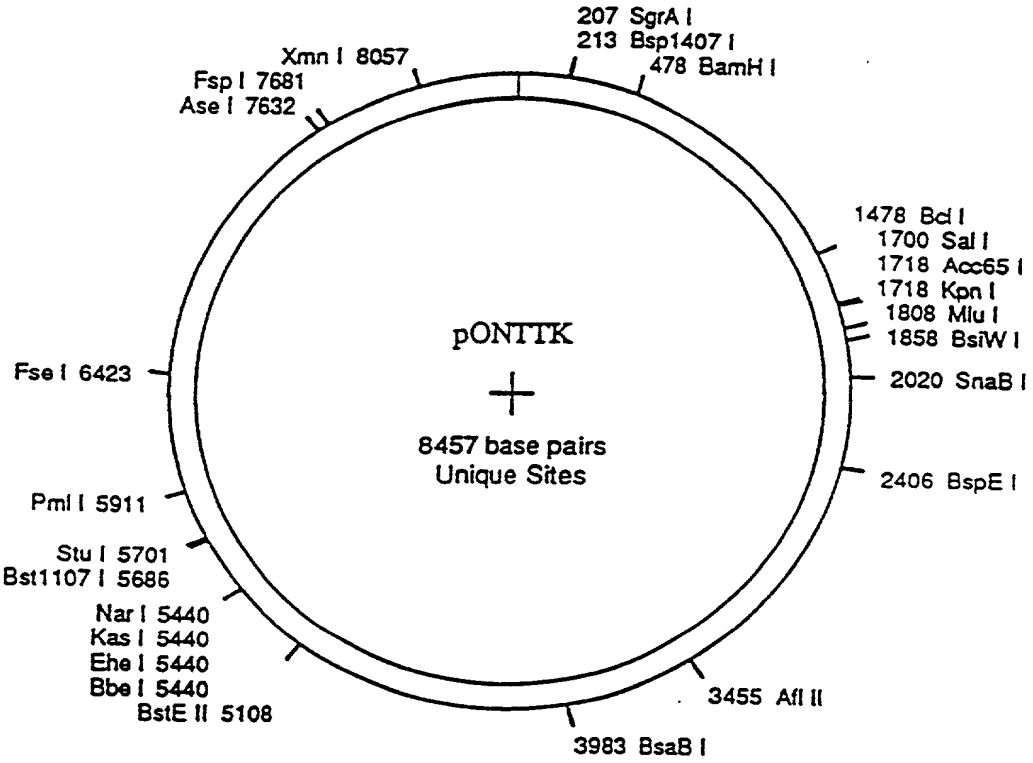
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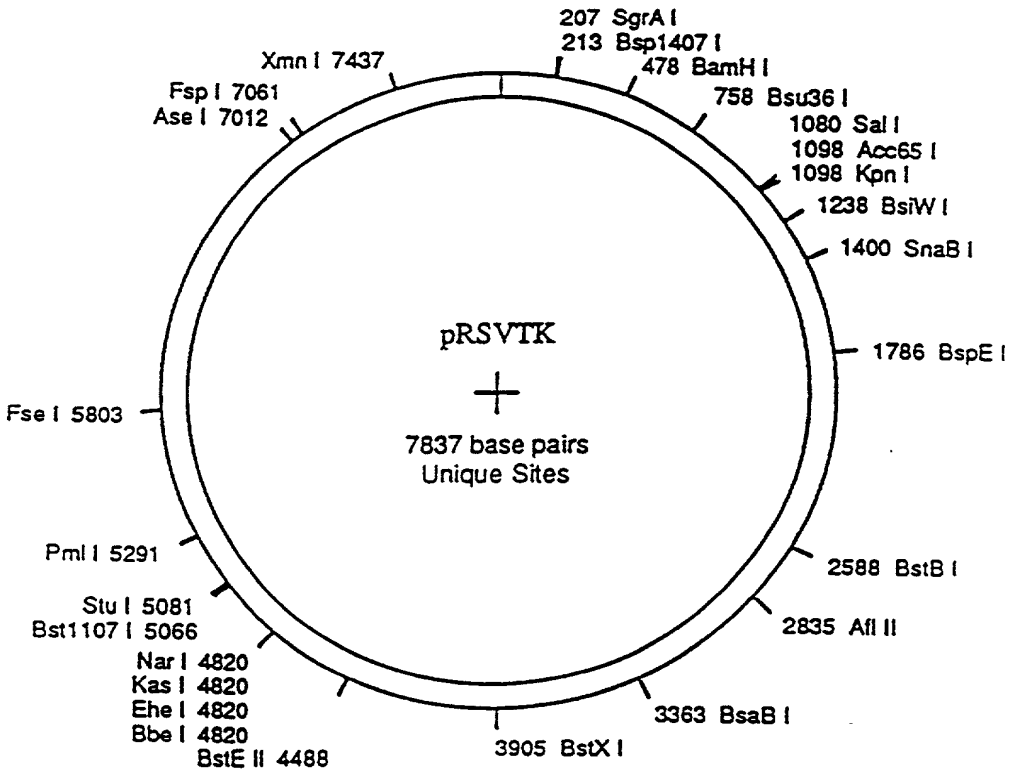
1478 Bcl I
1700 Sal I
1718 Acc65 I
1718 Kpn I
1808 Mlu I
1858 BsiW I
2020 SnaB I
2406 BspE I
3455 Afl II
3983 BsaB I
BstE II 5108
Bbe I 5440
Ehe I 5440
Kas I 5440
Nar I 5440
Bst1107 I 5686
Stu I 5701
Pml I 5911
Fse I 6423
Ase I 7632
Fsp I 7681
Xmn I 8057
pONTTK
8457 base pairs
Unique Sites

FIG. 1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1786 BspE I
2588 BstB I
2835 Afl II
3363 BsaB I
3905 BstX I
4820 BstE II 4488
4820 Bbe I
4820 Ehe I
4820 Kas I
4820 Nar I
5066 Bst1107 I
5081 Stu I
5291 Pml I
5803 Fse I
7012 Ase I
7061 Fsp I
7437 Xmn I
pRSVTK
7837 base pairs
Unique Sites

FIG. 2

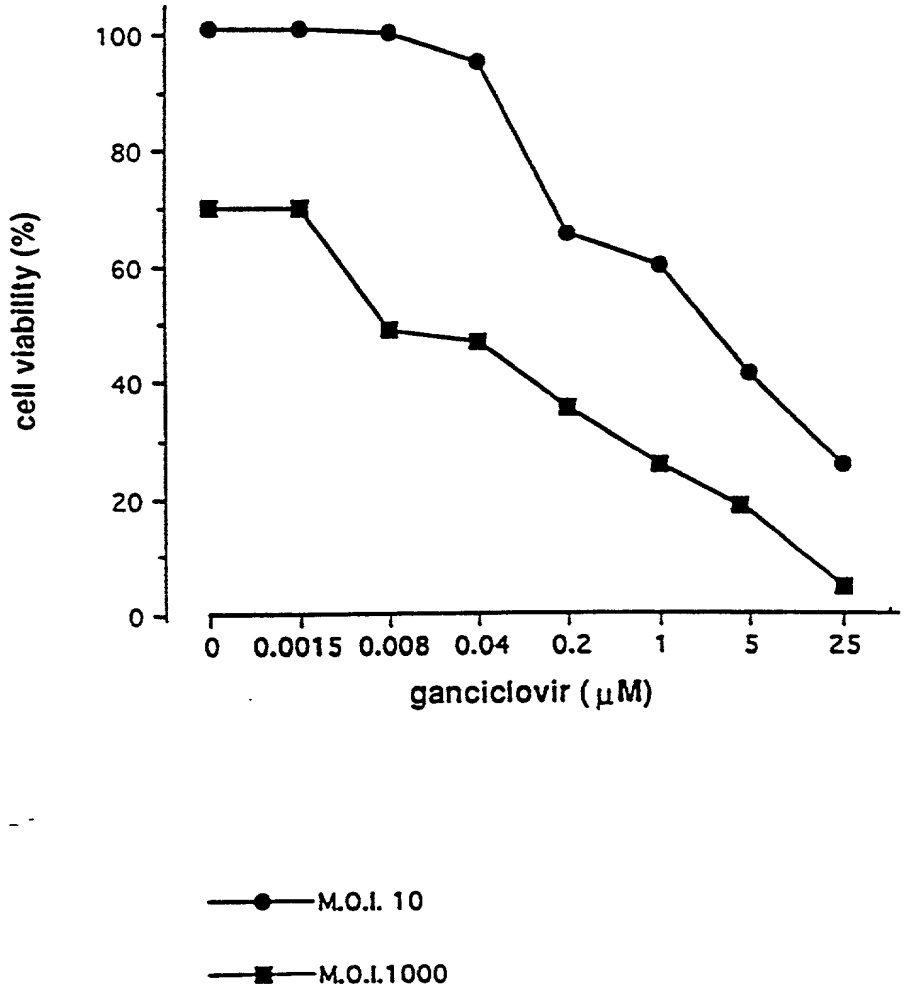
100
80
60
40
20
0
cell viability (%)
0
0.0015
0.008
0.04
0.2
1
5
25
ganciclovir (μM)
M.O.I. 10
M.O.I.1000

FIG. 3

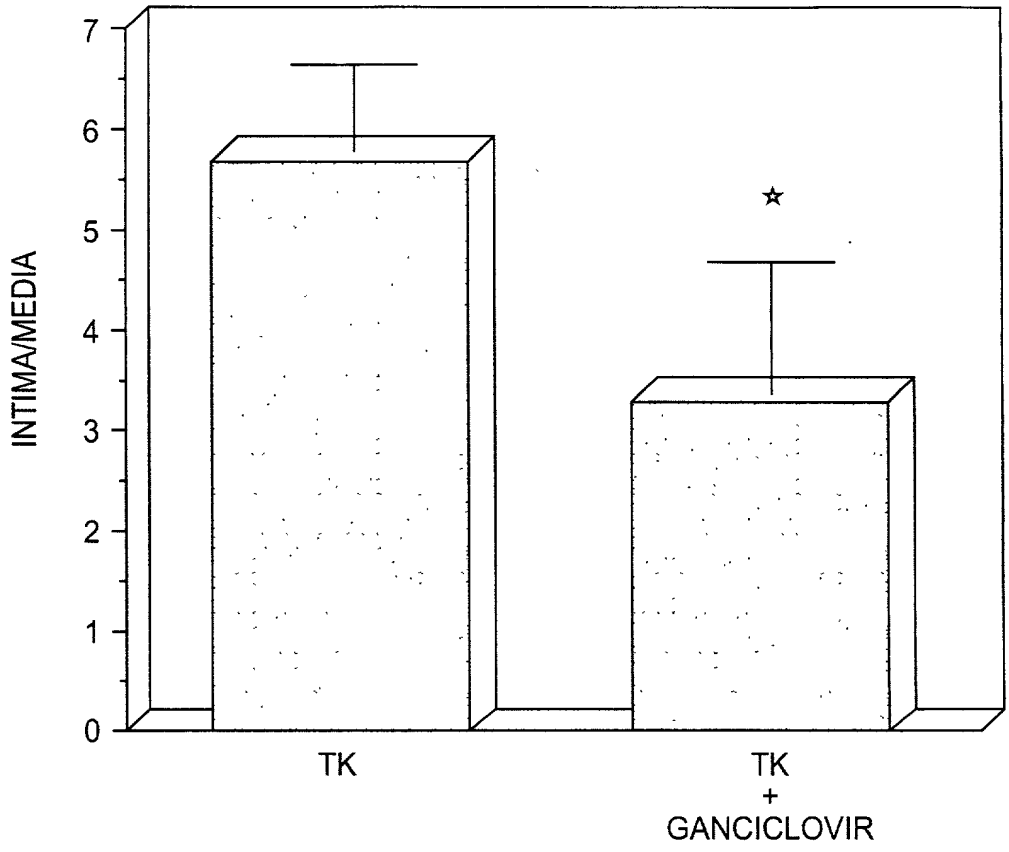

FIG. 4